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Valneva and Pfizer Report Further Positive Phase 2 Data for Lyme Disease Vaccine Candidate

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- **Dose selection complete for planned Phase 3 trial, expected to be initiated in 3Q2022**
- **Sub-analysis compared the immunogenicity of VLA15 in adults 18-65 years of age after administration of two or three primary series doses**
- **Stronger immune response observed in adult participants who received three priming doses vs. two priming doses; pediatric study ongoing with initial data expected in 1H2022**
- **Three-dose priming schedule selected for use in adults moving forward**

Saint-Herblain (France) and New York, February 4, 2022 – Valneva SE (Nasdaq: VALN; Euronext Paris: VLA), a specialty vaccine company, and Pfizer Inc. (NYSE: PFE) today reported further positive Phase 2 data for their Lyme disease vaccine candidate, VLA15. Based on these new results, Valneva and Pfizer plan to proceed with a three-dose primary series vaccination schedule in a planned Phase 3 clinical trial. The trial will evaluate VLA15 in adults and pediatric subjects 5 years of age and above and is expected to be initiated in 2022, subject to regulatory approval.

The Phase 2 trial, VLA15-221, compared the immunogenicity of VLA15 after administration of two (at months 0 and 6) or three (at months 0, 2 and 6) primary series doses in groups aged 5-11, 12-17 and 18-65 years. In the sub-analysis of adult participants (18-65 years old) who received VLA15 in either the two-dose schedule (N=90) or the three-dose schedule (N=97), performed one month after the last vaccination dose, VLA15 was found to be immunogenic with both vaccination schedules tested. These data are consistent with the strong immunogenicity profile observed for this age group in previous Phase 2 studies. However, the induction of anti-OspA IgG (anti-outer surface protein A immunoglobulin G) antibody titers was higher in participants who received the three-dose primary series compared to those who received the two-dose primary series, supporting the use of a three-dose primary series schedule in the planned Phase 3 clinical trial. The VLA15-221 trial is ongoing to assess the safety and immunogenicity of VLA15 in 5-17 year olds. Initial pediatric data are expected in the first half of 2022.

The analysis was also consistent with the acceptable safety and tolerability profile observed in previous studies of VLA15. No vaccine-related serious adverse events (SAEs) were observed.

Juan Carlos Jaramillo M.D., Chief Medical Officer of Valneva, said, “I’m very pleased with these results, which are critical for determining the optimal vaccination schedule for our planned Phase 3 trial. In partnership with Pfizer, we are excited to further investigate this vaccine candidate, which will hopefully help provide protection against Lyme disease for both adults and children.”

Kathrin U. Jansen, Ph.D., Senior Vice President and Head of Vaccine Research & Development at Pfizer, said: “Lyme disease is increasingly impacting people throughout the northern hemisphere, potentially due to environmental changes and more active outdoor lifestyles. The continued positive data from the VLA15-221

trial support the ongoing development of this vaccine candidate, and we look forward to continuing to work with Valneva to potentially help protect people against Lyme disease."

About VLA15
VLA15 is the only Lyme disease vaccine candidate currently in clinical development. This investigational multivalent protein subunit vaccine uses an established mechanism of action for a Lyme disease vaccine that targets the outer surface protein A (OspA) of Borrelia burgdorferi, the bacteria that cause Lyme disease. OspA is one of the most dominant surface proteins expressed by the bacteria when present in a tick. The vaccine covers the six OspA serotypes expressed by Borrelia burgdorferi sensu lato species that are prevalent in North America and Europe. VLA15 has demonstrated strong immunogenicity and safety data in pre-clinical and clinical studies so far. The program was granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in July 2017[1]. Valneva and Pfizer entered into a collaboration agreement in April 2020 to co-develop VLA15.[2]

About Clinical Study VLA15-221
VLA15-221 is a randomized, observer-blind, placebo-controlled Phase 2 study. It is the first clinical study with VLA15 that enrolls a pediatric population aged 5 years and older.

294 healthy adult participants received VLA15 at two different immunization schedules (month 0-2-6 [N=97] or month 0-6 [N=90]) or three doses of placebo (month 0-2-6 [N=107]). Vaccine recipients received VLA15 at a dose of 180 µg, which was selected based on data generated in the two previous Phase 2 studies. The main safety and immunogenicity readout in adults was performed at month 7. A subset of participants will receive a booster dose of VLA15 or placebo at month 18 (booster phase) and will be followed for three additional years to monitor antibody persistence. The VLA15-221 trial is ongoing to assess the safety and immunogenicity of VLA15 in a pediatric population aged 5 years and above.

VLA15 is tested as an alum-adjuvanted formulation and administered intramuscularly. The study is conducted at sites located in areas where Lyme disease is endemic and has enrolled volunteers with a cleared past infection with Borrelia burgdorferi as well as Borrelia burgdorferi-naïve volunteers.

About Lyme Disease
Lyme disease is a systemic infection caused by Borrelia burgdorferi bacteria transmitted to humans by infected Ixodes ticks[3]. It is considered the most common vector-borne illness in the Northern Hemisphere. While the true incidence of Lyme disease is unknown, it is estimated to annually affect approximately 476,000 people in the United States[4] and 130,000 people in Europe[5]. Early symptoms of Lyme disease (such as a gradually expanding erythematous rash called Erythema migrans or more unspecific symptoms like fatigue, fever, headache, mild stiff neck, arthralgia or myalgia) are often overlooked or misinterpreted. Left untreated, the disease can disseminate and cause more serious complications affecting the joints (arthritis), the heart (carditis) or the nervous system. The medical need for vaccination against Lyme disease is steadily increasing as the disease footprint widens[6].

References
[1]Valneva Receives FDA Fast Track Designation for its Lyme Disease Vaccine Candidate VLA15
[2]Valneva and Pfizer Announce Collaboration to Co-Develop and Commercialize Lyme Disease Vaccine, VLA15
[3]Stanek et al. 2012, The Lancet 379:461–473
[4]Source: https://www.cdc.gov/lyme/stats/humancases.html
[5]Sykes RA, et al. An estimate of Lyme borreliosis incidence in Western Europe. Journal of Public Health 2017; 39(1): 74-81
[6]New Scientist, Lyme disease is set to explode and we still don't have a vaccine; March 29, 2017. https://www.newscientist.com/article/mg23431195-800-lyme-disease-is-set-to-explode-and-you-cant-protect-

yourself/

About Valneva SE
Valneva is a specialty vaccine company focused on the development and commercialization of prophylactic vaccines for infectious diseases with significant unmet medical need. The Company takes a highly specialized and targeted approach to vaccine development and then applies its deep understanding of vaccine science to develop prophylactic vaccines addressing these diseases. Valneva has leveraged its expertise and capabilities both to successfully commercialize two vaccines and to rapidly advance a broad range of vaccine candidates into and through the clinic, including candidates against Lyme disease, the chikungunya virus and COVID-19.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Valneva Laëtitia Bachelot-Fontaine VP Global Communications & European Investor Relations M +33 (0)6 4516 7099 laetitia.bachelot-fontaine@valneva.com Joshua Drumm, Ph.D. VP Global Investor Relations M +1 917 815 4520 joshua.drumm@valneva.com Pfizer Media Relations: PfizerMediaRelations@pfizer.com 212-733-1226 Investor Relations: IR@pfizer.com 212-733-4848 Valneva Forward-Looking Statements This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing, results and completion of research, development and clinical trials for product candidates and estimates for future performance. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be sustained in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise. Pfizer Disclosure Notice The information contained in this release is as of February 4, 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. This release contains forward-looking information about a Lyme disease vaccine candidate, VLA15, and a collaboration between Pfizer and Valneva for VLA15, including their potential benefits and a potential phase 3

clinical trial, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for VLA15; whether and when any such applications may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether VLA15 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VLA15; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments. A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.